

REMARKS

This application has been reviewed in light of the Final Office Action mailed on April 27, 2004. Please consider Applicant's request for continued examination. Claims 1-3, 6, 9-11 and 19-30 are pending in the application with Claims 1, 9, 22 and 30 being in independent form. By the present amendment, Claims 1, 3, 9, 11, 21, 22, 24, 26, 27 and 28 have been amended and Claim 30 has been added. No new matter or issues are believed to be introduced by the amendments.

In the Final Office Action, Claims 1, 2, 9-11, 22, 23, 26 and 28 were rejected under 35 U.S.C. §102(b) as being anticipated over U.S. Patent No. 5,431,663 issued to Carter on July 11, 1995 ("Carter"). Independent Claims 1, 9 and 22 have been amended in a manner which is believed to better define Applicant's invention and to overcome the rejection.

Independent Claim 1 has been amended to recite:

A method for treating an external wound from a non-contact distance d,
comprising the steps of:

positioning an ultrasound transducer such that a distal radiation surface of the ultrasound transducer is positioned at a distance substantially equal to the non-contact distance d from the surface of the external wound; and

creating and maintaining ultrasound standing waves between the surface of the external wound and the distal radiation surface, wherein the ultrasound standing waves are created and maintained in air along the non-contact distance d, wherein the non-contact distance d is determined by the formula: $d = n \times \lambda/2$, where λ is the wavelength of an ultrasound standing wave and n is a positive integer, and wherein the ultrasound standing waves create radiation pressure for providing a bactericidal and a therapeutic effect to the external wound for decreasing the healing time for the external wound.
(Emphasis added)

Carter does not disclose or suggest the newly added limitations to Applicant's Claim 1.

In particular, Carter does not disclose or suggest a method for treating an external wound from a non-contact distance d as recited by the preamble of Applicant's Claim 1. Further, Carter does

not disclose or suggest positioning an ultrasound transducer such that a distal radiation surface of the ultrasound transducer is positioned at a distance substantially equal to the non-contact distance d from the surface of the external wound, as recited by Applicant's Claim 1. Further still, Carter does not disclose or suggest creating and maintaining ultrasound standing waves between the surface of the external wound and the distal radiation surface, wherein the ultrasound standing waves are created and maintained in air along the non-contact distance, as recited by Applicant's Claim 1.

Independent Claim 9 has been amended to recite:

A system for treating an external wound with ultrasound standing waves from a non-contact distance, comprising:

means for generating ultrasound waves including an ultrasound transducer having a distal radiation surface; and

means for creating and maintaining ultrasound standing waves in air by adjusting the non-contact distance between the distal radiation surface and the external wound, wherein the ultrasound standing wave create radiation pressure for providing a bactericidal and a therapeutic effect to the external wound for decreasing the healing time for the external wound. (Emphasis added)

Carter does not disclose or suggest the newly added limitations to Applicant's Claim 9.

In particular, Carter does not disclose or suggest a system for treating an external wound with ultrasound standing waves from a non-contact distance, as recited by the preamble of Applicant's Claim 9. Further, Carter does not disclose or suggest means for creating and maintaining ultrasound standing waves in air by adjusting the non-contact distance between the distal radiation surface and the external wound, as recited by Applicant's Claim 9.

Independent Claim 22 has been amended to recite:

A method for treating an external wound from a non-contact distance comprising the steps of:

providing a transducer having a distal radiation surface arranged at the non-

contact distance from the surface of the external wound for emitting ultrasonic waves;
and

creating and maintaining ultrasound standing waves in air between the surface of the external wound and the distal radiation surface by adjusting the non-contact distance, wherein the ultrasound standing waves create radiation pressure for providing a bactericidal and a therapeutic effect to the external wound for decreasing the healing time for the external wound. (Emphasis added)

Carter does not disclose or suggest the newly added limitations to Applicant's Claim 22.

In particular, Carter does not disclose or suggest providing a transducer having a distal radiation surface arranged at a non-contact distance from the surface of the external wound for emitting ultrasonic waves, as recited by Applicant's Claim 22. Further, Carter does not disclose or suggest creating and maintaining ultrasound standing waves in air between the surface of the external wound and the distal radiation surface by adjusting the non-contact distance, as recited by Applicant's Claim 22.

Carter teaches how to create constant ultrasonic vibrational amplitude at the radiator/transducer tip site by changing the length of piezoelectric crystal for preventing loss of acoustic power (see column 4, lines 33-48). According to Carter, the creation of sufficient length of piezoelectric crystal avoids the loss of amplitude at resonance (column 4, lines 50-68), due to the occurrence of ultrasound standing waves **inside** of the device, between rear face 36 of piezocrystal and radiating surface 48 of guide/amplifier 58 (see Figure 2), and not between a distal radiation surface of an ultrasound transducer and the external wound as recited by Applicant's Claims 1, 9 and 22.

Further, Carter teaches using sufficient piezoelectric crystal length from 1.25 to 12.5 mm in an operating frequency range of 50kHz to 1.3MHz to maintain and cause cavitation for disruption and liquefaction of blood clots and plaque when the radiator/transducer tip site of the

device is placed inside the blood clot (see col. 7, lines 19-23). In the contrary, Applicant's Claims 1, 9 and 22 recite decreasing the healing time of an external wound by creating and maintaining ultrasound standing waves in air between the external wound and the distal radiation surface of an ultrasound transducer. Accordingly, withdrawal of the rejection under 35 U.S.C. §102(b) and allowance of Claims 1, 9 and 22 are respectfully requested.

Claims 2, 10, 11, 23, 26 and 28 depend from either Claim 1, 9 or 22, and therefore include the limitations of either Claim 1, 9 or 22. Accordingly, for the same reasons given for Claims 1, 9 and 22, Claims 2, 10, 11, 23, 26 and 28 are believed to contain patentable subject matter. Accordingly, withdrawal of the rejection under 35 U.S.C. §102(b) and allowance of Claims 2, 10, 11, 23, 26 and 28 are respectfully requested.

Claims 1, 2, 9, 10, 19-23, 25 and 29 were rejected under 35 U.S.C. §102(b) as being anticipated over U.S. Patent No. 6,007,499 issued to Martin et al. on December 28, 1999 ("Martin et al."). Independent Claims 1, 9 and 22 have been amended in a manner which is believed to better define Applicant's invention and to overcome the rejection.

With respect to Claim 1, Martin et al. does not disclose or suggest the newly added limitations to Applicant's Claim 1. In particular, Martin does not disclose or suggest a method for treating an external wound from a non-contact distance d as recited by the preamble of Applicant's Claim 1. Further, Martin et al. does not disclose or suggest positioning an ultrasound transducer such that a distal radiation surface of the ultrasound transducer is positioned at a distance substantially equal to the non-contact distance d from the surface of the external wound, as recited by Applicant's Claim 1. Further still, Martin et al. does not disclose or suggest creating and maintaining ultrasound standing waves between the surface of the external wound

and the distal radiation surface, wherein the ultrasound standing waves are created and maintained in air along the non-contact distance, as recited by Applicant's Claim 1.

With respect to Claim 9, Martin et al. does not disclose or suggest the newly added limitations to Applicant's Claim 9. In particular, Martin et al. does not disclose or suggest a system for treating an external wound with ultrasound standing waves from a non-contact distance, as recited by the preamble of Applicant's Claim 9. Further, Martin et al. does not disclose or suggest means for creating and maintaining ultrasound standing waves in air by adjusting the non-contact distance between the distal radiation surface and the external wound, as recited by Applicant's Claim 9.

With respect to Claim 22, Martin et al. does not disclose or suggest the newly added limitations to Applicant's Claim 22. In particular, Martin et al. does not disclose or suggest providing a transducer having a distal radiation surface arranged at a non-contact distance from the surface of the external wound for emitting ultrasonic waves, as recited by Applicant's Claim 22. Further, Martin et al. does not disclose or suggest creating and maintaining ultrasound standing waves in air between the surface of the external wound and the distal radiation surface by adjusting the non-contact distance, as recited by Applicant's Claim 22.

Martin et al. teaches placing an apparatus in contact with the patient and emitting high intensity focused ultrasound ("HIFU") to form cauterized tissue regions **within the body** prior to surgical incision. At best, Martin shows superposition of incident and reflected ultrasound waves inside of the tissue, and does not teach creating and maintaining ultrasound standing waves in air between a distal radiation surface of an ultrasound transducer and an external wound, as recited by Applicant's Claims 1, 9 and 22. Accordingly, withdrawal of the rejection under 35 U.S.C.

§102(b) and allowance of Claims 1, 9 and 22 are respectfully requested.

Claims 2, 10, 19-21, 23, 25 and 29 depend from either Claim 1, 9 or 22, and therefore include the limitations of either Claim 1, 9 or 22. Accordingly, for the same reasons given for Claims 1, 9 and 22, Claims 2, 10, 19-21, 23, 25 and 29 are believed to contain patentable subject matter. Accordingly, withdrawal of the rejection under 35 U.S.C. §102(b) and allowance of Claims 2, 10, 19-21, 23, 25 and 29 are respectfully requested.

Claims 3 and 24; Claims 20 and 25; and Claims 6 and 27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Carter '663 or Martin et al. '499; over Carter '663; and over Carter '663 in view of Briskin '811, respectively.

Claims 3, 6, 20, 24, 25 and 27 depend from either Claim 1 or 22, and therefore include the limitations of either Claim 1 or 22. Accordingly, for the same reasons given for Claims 1 and 22, Claims 3, 6, 20, 24, 25 and 27 are believed to contain patentable subject matter.

Additionally, with respect to Carter '663 and Briskin '811, these patents teach the placement of an ultrasound transducer within a blood vessel. As mentioned above, Carter '663 uses the phenomena of the occurrence of standing waves inside of a device having a piezocrystal to increase amplitude and prevent loss of acoustic power. Briskin '811 teaches the use of two tubular transducer assemblies in a catheter body to create standing waves between radial radiation surface (not distal radiation surface) of transducer and vascular wall. The standing waves created between the radial radiation surface and vascular wall produce a shearing effect on the vascular wall for dissolving clots or plaque in front of the transducer (no standing waves are created in front of the transducer). In the contrary, Applicant's independent Claims 1, 9 and 22 which are further limited by dependent Claims 3, 6, 20, 24, 25 and 27 recite the positioning of an

ultrasound transducer at a non-contact distance from the surface of an external wound for creating and maintaining ultrasound standing waves in air between a distal radiation surface of the ultrasound transducer and the external wound. Accordingly, withdrawal of the rejection under 35 U.S.C. §103(a) and allowance of Claims 3, 6, 20, 24, 25 and 27 are respectfully requested.

New Claim 30 recites limitations which are not disclosed or suggested by the art of record. Accordingly, allowance of new Claim 30 is respectfully requested.

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims presently pending in the application, namely, Claims 1-3, 6, 9-11 and 19-30, are believed to be in condition for allowance and patentably distinguishable over the art of record.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call Applicant's undersigned attorney at (631) 501-5706.

Respectfully submitted,



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